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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,351	03/19/2001	Sidney T. Smith	CRTS-5679 (1417A P 450)	3473

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EXAMINER	
PASCUA, JES F	

ART UNIT	PAPER NUMBER
3727	22

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/813,351	SMITH ET AL.	
	Examiner	Art Unit	
	Jes F. Pascua	3727	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *24* is/are allowed.

6)☒ Claim(s) *1-15,17-23 and 25-35* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *18 & 19* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-9, 13-15, 17-20, 27, 28, 30 and 33 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Sugimoto et al. See Fig. 2.

As a note, the flexible container of Sugimoto et al. is capable of maintaining a sterile barrier to the same degree that applicant has defined the specific structure encompassed by the language "capable of maintaining a sterile barrier".

3. Claims 1-9, 13-15, 17-20, 27, 28, 30 and 33 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sugimoto et al. See Fig. 2.

As a note, the flexible container of Sugimoto et al. is capable of maintaining a sterile barrier to the same degree that applicant has defined the specific structure encompassed by the language "capable of maintaining a sterile barrier".

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 2, 6-11, 17, 30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. in view of Jones.

Cook et al. discloses the claimed device except for the interior volume of the flexible container being at least about 200 liters. Jones discloses that it is known in the art to provide an analogous flexible container that can have an interior volume as little as 10 liters to as high as 300 liters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the flexible container of Cook et al. with an interior volume of at least 200 liters; taught to be desirable by Jones, since a change in size is generally recognized as being within the level of ordinary skill in the art.

Furthermore, the flexible container of Cook et al. is capable of maintaining a sterile barrier to the same degree that applicant has defined the specific structure encompassed by the language "capable of maintaining a sterile barrier".

6. Claims 1-4, 6-9, 14, 17, 18, 20, 27, 31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calhoun in view of Jones.

Calhoun discloses the claimed device except for the interior volume of the flexible container being at least about 200 liters. Jones discloses that it is known in the art to provide an analogous flexible container that can have an interior volume as little as 10 liters to as high as 300 liters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the flexible container of Calhoun with an interior volume of at least 200 liters; taught to be desirable by Jones, since a change in size is generally recognized as being within the level of ordinary skill in the art.

Furthermore, the flexible container of Calhoun is capable of maintaining a sterile barrier to the same degree that applicant has defined the specific structure encompassed by the language "capable of maintaining a sterile barrier".

7. Claims 1, 2, 6-10, 13-15, 17, 27, 30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaFleur '335 in view of Jones.

LaFleur '335 discloses the claimed device except for the interior volume of the flexible container being at least about 200 liters. Jones discloses that it is known in the

art to provide an analogous flexible container that can have an interior volume as little as 10 liters to as high as 300 liters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the flexible container of LaFleur '335 with an interior volume of at least 200 liters; taught to be desirable by Jones, since a change in size is generally recognized as being within the level of ordinary skill in the art.

Furthermore, the flexible container of LaFleur '335 is capable of maintaining a sterile barrier to the same degree that applicant has defined the specific structure encompassed by the language "capable of maintaining a sterile barrier".

8. Claims 1-10, 12, 14, 15, 17-20, 27, 28, 30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al. in view of Jones.

Sasaki et al. discloses the claimed device except for the interior volume of the flexible container being at least about 200 liters. Jones discloses that it is known in the art to provide an analogous flexible container that can have an interior volume as little as 10 liters to as high as 300 liters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the flexible container of Sasaki et al. with an interior volume of at least 200 liters; taught to be desirable by Jones, since a change in size is generally recognized as being within the level of ordinary skill in the art.

Furthermore, the flexible container of Sasaki et al. is capable of maintaining a sterile barrier to the same degree that applicant has defined the specific structure encompassed by the language "capable of maintaining a sterile barrier".

Moreover, Sasaki et al. discloses the claimed invention, as discussed above, except for the sleeve-forming panels having end edges. It would have been obvious to a person having ordinary skill in the art at the time invention was made to provide the sleeve-forming panels of Sasaki et al. with end edges since it was known in the art that end edges (e.g. fold lines) facilitate the formation of flexible containers into their desired shape.

9. Claims 25, 26, 29, 32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugimoto et al. in view of LaFleur et al. '472.

Sugimoto et al. discloses the claimed device except for the top side of the container having a plurality of hanger connectors. LaFleur et al. '472 discloses that it is known in the art to provide a plurality of hanger connectors on the top side of an analogous container. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the top side of Sugimoto et al. with the hanger connectors of LaFleur et al. '472, in order to support the flexible container within the outer bag.

Regarding claim 35, Sugimoto et al. and LaFleur et al. '472 disclose the claimed invention, as discussed above, except for hanger connectors being located between 35% to about 65% of a length of the diagonal line. It would have been an obvious

matter of design choice to place the hanger connectors of LaFleur et al. '472 between 35% to about 65% of a length of the diagonal line, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

10. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al.

Sasaki et al. discloses the claimed invention except for the firs, second, third and fourth side panels being formed from individual films. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the side panels of Sasaki et al. from a single film, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

As a note, forming the side panels of Sasaki et al. from a single film, as discussed above, would eliminate the need for side seals 9 and inherently result in "the container structure being substantially free of projections" at the connection lines between the side panels below the top end of the container.

Furthermore, the flexible container of Sasaki et al. is capable of maintaining a sterile barrier to the same degree that applicant has defined the specific structure encompassed by the language "capable of maintaining a sterile barrier".

Allowable Subject Matter

11. Claim 24 is allowed.

12. Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

13. Applicant's arguments with respect to claims 1-35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jes F. Pascua whose telephone number is 703-308-1153. The examiner can normally be reached on Mon.-Thurs..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lee W. Young can be reached on 703-308-2572. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1078.

Jes F. Pascua
Primary Examiner
Art Unit 3727

JFP